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Our ref.: New German Patent Application
Novosis AG
Oxybutynin TDS

Transdermal drug delivery system for oxybutynin

WO 99/48 493 describes an oxybutynin patch obtained according to the socalled hot melt process. It is stated that the patch does not contain any enhancer. Nevertheless substances which are usually used as enhancers, are mentioned, especially citric acid triester.

US 5 601 839 describes triacetin as an agent improving permeability.

As regards oxybutynin patches, US 5 411 740 and WO 93/23 025 should also be mentioned.

The problem underlaying the invention is solved by a transdermal drug delivery system (TDS) comprising
- a cover which is impermeable for the active ingredient,
- a matrix containing oxybutynin as active ingredient and
- a facultative release liner, wherein the matrix further comprises
- an Aloe Vera extract,
- a pressure sensitive adhesive and
- a cross linking agent for the adhesive.

The transdermal drug delivery system according to the invention may comprise racemic oxybutynin, R-oxybutynin, S-oxybutynin or desethyl-oxybutynin.

Further, the pressure sensitive adhesive of the transdermal drug delivery system according the invention may comprise or consist of an acrylate based polymer, preferably a polymer based on an acrylate-vinyl acetate copolymer.

Further, the pressure sensitive adhesive of the transdermal drug delivery system according to the invention may comprise or consist of Durotak 2287 or Durotak 2516.

Further, the matrix of the transdermal drug delivery system according to the invention may comprise Ti-acetylacetonate, Al-acetylacetonate or polybutyl-titanate as crosslinking agent.

Further the extracting agent of the Aloe Vera-extract of the transdermal drug delivery system according to the invention may be a vegetable oil, preferably soybean oil.

An Aloe Vera-extract is available from, for example, Caesar & Loretz (Hilden/Germany).

Further, the Aloe Vera-extract of the transdermal drug delivery system according to the invention may comprise 5 to 15 % by weight of Aloe Vera oil and 95 to 85 % by weight of the vegetable oil.

Further, the matrix of the transdermal drug delivery system according to the invention may comprise the Aloe Vera-extract as the only enhancer.

Further, the matrix of the transdermal drug delivery system according to the invention may comprise 5 to 40, preferably 10 to 35 and especially 15 to 30 % by weight of oxybutynin (based on the matrix).

Further, the matrix of the transdermal drug delivery system according to the invention may comprise 10 to 25, preferably 12 to 20 and especially 14 to 18 % by weight of Aloe Vera-extract (based on the matrix).

Further, the matrix of the transdermal drug delivery system according to the invention may comprise 0.1 to 5.0, preferably 0.3 to 3 and especially 0.5 to 2.0 % by weight of the crosslinking agent (based on the matrix).

The transdermal drug delivery system according to the invention may have a surface of 5 to 80, preferably 10 to 60 and especially 20 to 50 cm^2.

Example and comparative example

A composition of a matrix according to the invention was provided as follows:

Oxybutynin	20.0 %
Aloe Vera-extract (soy bean oil)	15.0 %
Ti-acetylacetonate (Tyzor AA 75)	1.3 %
Durotak 2287	remainder

This composition was subjected to a permeation test (mouse skin). The maximum flux was 9.2 $\mu g/cm^2/h$. The permeation was 190 $\mu g/cm^2/24$ h.

According to US 5 601 839 a matrix was provided with the following composition.

Oxybutynin	20.0 %
Triacetin	15.0 %
Al-Acetylacetonate	0.5 %
Durotak 2051 (Acrylate/Vinylacetate adhesive)	remainder

This composition was also subjected to a permeation test (mouse skin). The maximum flux was 5.3 $\mu g/cm^2/h$. The permeation was 80 $\mu g/cm^2/24$ h.